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October 18, 2011

VIA ECF & FEDEX

The Honorable Patty Shwartz, U.S.M.J.
United States District Court
U.S.P.O. & Courthouse Bldg., Room 477
One Federal Square
Newark, New Jersey 07102

Re: *Prometheus Laboratories Inc. v. Roxane Laboratories, Inc.*
Civil Action No. 11-1241 (FSH)(PS)

Dear Judge Shwartz:

Pursuant to the Court's Order entered October 4, 2011 (D.I. 31), Prometheus Laboratories Inc. ("Prometheus") and Roxane Laboratories, Inc. ("Roxane") submit this joint letter to identify Prometheus' outstanding disputes regarding Roxane's responses to Prometheus' discovery requests.[1]

PROMETHEUS' POSITIONS

After several meet-and-confers the parties reached an impasse on a few remaining disputes related to Roxane's discovery request responses, which we respectfully request the Court to address at the upcoming October 21, 2011 conference.

As discussed below in the context of specific disputed Document Requests and Interrogatories, Roxane has unilaterally decided that certain categories of discovery are irrelevant and has improperly refused to produce responsive documents and information. Specifically, with

[1] Portions of Prometheus' First Set of Requests for the Production of Documents and Things (Nos. 1-87) and First Set of Interrogatories (Nos. 1-15) are respectively attached as Exhibits A and B. Relevant portions of Roxane's responses to Prometheus' First Set of Requests for the Production of Documents and Things (Nos. 1-87) and First Set of Interrogatories (Nos. 1-15) are respectively attached as Exhibits C and D.

respect to its accused ANDA product, Roxane seeks to limit its production to its ANDA and documents filed with or received from the FDA. Roxane refuses to produce (1) documents ***concerning*** the ANDA or FDA filings, including internal documents and draft FDA filings and Risk Evaluation and Mitigation Strategies ("REMS") for its proposed product; (2) any documents concerning the sales and marketing of its ANDA product; and (3) any discovery concerning its knowledge of the patent-in-suit and its non-infringement and invalidity contentions in this matter. The disputed discovery is relevant to at least Prometheus' case of infringement against Roxane. Accordingly, Prometheus respectfully requests that the Court order Roxane to produce the requested documents and information.

A. Documents Concerning Roxane's Alosetron Products and ANDA (Request Nos. 2-4, 53 and 58-60)

Prometheus' Request No. 2 seeks all documents concerning Roxane's ANDA. Request No. 3 seeks all communications between Roxane and the FDA concerning its ANDA and all documents concerning such communications. Request No. 4 seeks all documents concerning Roxane's ANDA products. Request Nos. 53 and 58-60 seek documents concerning REMS for Roxane's ANDA product and LOTRONEX®. These requests all concern the accused product and ANDA directly at issue in this litigation. Yet, Roxane seeks to limit its production in response to these requests to its actual ANDA filings and has refused to produce documents ***concerning*** the ANDA or its ANDA Products, including internal documents and any draft FDA submissions.

Roxane misleadingly maintains that it is producing documents concerning the use of its ANDA product. This is directly contradicted by its refusal to produce any draft submissions or communications relating to its ANDA or internal documents concerning Roxane's knowledge and intent concerning its ANDA product and the use of its ANDA product. Indeed, Roxane refuses to produce internal documents considered by Roxane in designing, developing or implementing Roxane's REMS and documents related to Roxane's actual as well as any contemplated and draft REMS for its ANDA products which address the safe and effective use of alosetron hydrochloride. Roxane's refusal to produce the full scope of the requested discovery is improper.

Roxane's contention that the requested documents are not relevant is simply wrong. In a Hatch-Waxman infringement case, like this one, the Court focuses its infringement inquiry on the accused product that the defendant will market upon FDA approval. *See Abraxis Bioscience, Inc. v. Navinta, LLC*, 640 F. Supp. 2d 553, 569 (D.N.J. 2009). As such, courts routinely order production of documents concerning the accused product, such as documents concerning ANDAs, because such documents are necessarily relevant. *See Conopco, Inc. v. Warner-Lambert Co.*, Civ. No. 99-101 (KSH), 1999 WL 1565082, at *6 (D.N.J. Jan. 24, 2000); *Astellas Pharma, Inc. v. Impax Labs., Inc.*, Civ. No. 08-3466, 2009 WL 2392166 (N.D. Cal. Aug. 4, 2009); *Kamatani v. BenQ Corp.*, Civ. No. 2:03-CV437, 2005 WL 2455825, at *1-2 (E.D. Tex. Oct. 6, 2006).

Here, Prometheus' complaint alleges that Roxane's filing of its ANDA seeking approval to market an alosetron hydrochloride product infringes the '770 patent. Accordingly, internal documents concerning Roxane's ANDA and ANDA product are central to the infringement issues in this action. The scope of discovery on Roxane's accused product and its use should not be limited to what is essentially the FDA-submitted ANDA filings alone. Accordingly, we request that Roxane be ordered to produce all documents and things responsive to the full scope of Prometheus' Request Nos. 2-4, 53 and 58-60. This includes all internal or draft documents concerning its ANDA products, ANDA, or actual or proposed REMS for its ANDA product or LOTRONEX®.

B. Documents Concerning Sales/Revenue Projections and Business Plans (Request Nos. 22-24)

Prometheus' Request Nos. 22 and 23 seek all documents concerning projections and estimates of sales or revenues for Roxane's ANDA products. Request No. 24 seeks all documents concerning business or strategic plans relating to the marketing and sale of Roxane's ANDA products. Roxane's refusal to produce documents based on boilerplate objections to these requests is improper. Roxane cannot dispute that its attempt to market and sell its ANDA product is the basis for this infringement suit. The requested documents are likely to contain information concerning who will be prescribing and using its proposed product, and how Roxane expects those products to be used. Accordingly, the requested documents are relevant at least to the issue of infringement.

Moreover, Roxane intends to dispute the fact that LOTRONEX® is a commercially successful product. The sales of a generic product are directly related to sales and the commercial success of its equivalent. In that regard, Roxane will not have a sales force that is out in the marketplace encouraging doctors to prescribe its generic version of LOTRONEX®. Instead, Roxane's sales will depend on pharmacists substituting its generic product for prescriptions written by doctors for LOTRONEX®. Thus, Roxane's sales projections and market projections go directly to the issue of whether Roxane believes that LOTRONEX® is a commercial success. Roxane's projections concerning sales of LOTRONEX® and its generic product would also be relevant to Roxane's incentive and motivation for copying the claimed invention of the patents-in-suit. The commercial success of LOTRONEX® and copying are both relevant to rebutting Roxane's obviousness defense. Consequently, Roxane's refusal to produce the requested documents is improper and Roxane should be compelled to produce documents responsive to the full scope of Request Nos. 22-24.

C. Roxane's "Knowledge" Regarding the '770 Patent Infringement and Validity (Interrogatory Nos. 3 and 10)

Prometheus' Interrogatory No. 3 seeks identification of persons employed by Roxane who are most knowledgeable concerning its infringement and the validity of the '770 patent. Interrogatory No. 10 calls for Roxane to describe the circumstances under which it became aware of the reexamination proceedings concerning the patent-in-suit, and to identify the persons

employed by Roxane who are most knowledgeable of such circumstances. Roxane merely refers Prometheus to Roxane's Invalidity and Non-Infringement Contentions, but otherwise refuses to provide a substantive response to these interrogatories.

Roxane's knowledge of the '770 patent and the circumstances under which it became aware of the reexamination proceedings, and whether its conduct would cause infringement of that patent are highly relevant to the issues of inducement. As recently explained by the U.S. Supreme Court, "induced infringement under §271(b) requires knowledge that the induced acts constitute patent infringement." *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S.Ct. 2060, 2068 (2011). This requirement places Roxane's knowledge of the '770 patent, and any analysis of whether the use of its proposed product would infringe the '770 patent, squarely at issue in this action. Roxane's assertion that it does not infringe the asserted claims because those claims are invalid also places its knowledge of its invalidity defenses at issue. Accordingly, Roxane should be compelled to provide substantive responses to Interrogatory Nos. 3 and 10.

D. Identification of Opinions or Advice Regarding the '770 Patent (Interrogatory No. 5)

Prometheus' Interrogatory No. 5 seeks identification of any opinions or advice regarding the meaning, validity, infringement, enforceability, and scope of any claims of the patent-in-suit. Identification of opinions and advice concerning the '770 patent is likely to lead to the discovery of admissible evidence concerning the validity and infringement of the patent-in-suit. Meanwhile, Roxane fails to articulate any reasonable basis for withholding non-privileged information in response to this interrogatory.

Indeed, Roxane's only stated reason for withholding this information is that Prometheus' interrogatory is "premature in view of Local Rule 2.3(d)." This argument has no merit. L.Pat.R. 2.3(d) provides that it may be proper to object as premature to a discovery request that seeks the identification of advice of counsel that "each party is relying upon . . . as part of a patent-related claim or defense for any reason []." L.Pat.R. 2.3(d) (2011). Here, Interrogatory No. 5 does not only seek identification of opinions that Roxane intends to rely upon to support its defenses in this action. It is also not limited to attorney-client communications and other discovery that is necessarily protected by the attorney-client privilege. Accordingly, Roxane should be compelled to provide a substantive response to Interrogatory No. 5.

ROXANE'S POSITIONS[2]

Prometheus has mischaracterized the categories of discovery that Roxane has agreed to produce (and the documents that Roxane has not agreed to produce) in this litigation. Roxane does not seek "to limit its production to its ANDA and documents filed with or received from the FDA." Roxane has agreed to produce all discovery that can reasonably be considered relevant to the issues in this case.

Prometheus's complaint alleges that the filing of Roxane's ANDA No. 200-652 ("Roxane's ANDA"), which seeks FDA approval to sell Roxane's generic alosetron hydrochloride products ("Roxane's ANDA products"), infringes the '770 patent. The '770 patent is a method of use patent. It claims methods of using alosetron for the treatment of a subpopulation of female diarrhea-predominant irritable bowel syndrome ("IBS-D") patients. Roxane contends that the '770 patent is invalid and not infringed. In view of the issues in this case, Roxane has agreed to produce Roxane's ANDA and all amendments and supplements thereto, and at least the following categories of non-privileged documents:

- documents concerning the use of Roxane's ANDA products for any purpose;
- documents concerning the REMS that Roxane has proposed to the FDA;
- documents concerning the use of any alosetron product, including LOTRONEX®, for treating IBS;
- documents concerning the '770 patent;
- prior art; and
- actual LOTRONEX® sales.

In its interrogatory responses, Roxane has identified individuals knowledgeable regarding: (1) the filing of Roxane's ANDA; (2) Roxane's ANDA products; and (3) the use of Roxane's ANDA products.

In sum, Roxane is not withholding from production any discovery that is relevant to the questions of infringement and validity in this case.

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2 In this letter, Prometheus does not challenge Roxane's objection to producing documents other than FDA correspondence created or dated on or after the filing of the complaint in this action in January 2011. To the extent Prometheus changes its position, Roxane reserves the right to respond.

A. Documents Concerning Roxane's Alosetron Products and ANDA (Request Nos. 2-4, 53 and 58-60)

Prometheus's Request Nos. 2-4 seek all documents concerning Roxane's ANDA, Roxane's ANDA products, and communications with the FDA regarding Roxane's ANDA. Roxane produced its ANDA to Prometheus on May 17, 2011 and is producing amendments and FDA correspondence on a rolling basis. Roxane is also producing all non-privileged documents concerning the use of Roxane's ANDA products for any purpose.

Prometheus's complaint alleges infringement of the '770 ***method of use*** patent directed to the use of alosetron to treat a subpopulation of female IBS patients. The '770 patent does not claim the compound alosetron or a pharmaceutical formulation containing alosetron. Nevertheless, Prometheus seeks the production of irrelevant documents concerning, for example, Roxane's API, the formulation of Roxane's ANDA products, dissolution studies, stability tests, communications with Roxane's API supplier, and the decision to use a particular formulation for Roxane's ANDA products. Those documents have no bearing on the infringement or validity of the '770 patent. Moreover, there is no dispute that Roxane's ANDA products contain alosetron. Roxane maintains its objections, therefore, to producing documents that do not concern the ***use*** of Roxane's ANDA products.

Furthermore, Prometheus has no cognizable ground for requesting draft FDA filings. The infringement inquiry focuses on what Roxane will likely sell if its ANDA is approved. Such a "hypothetical inquiry is properly grounded in the ANDA application and the extensive materials typically submitted in its support." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). The infringement analysis is limited to an analysis of "whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed." *Warner-Lambert Co.* v. *Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). Draft documents that Roxane did not file with the FDA do not help analyze what Roxane seeks FDA authorization to sell. Those documents are not relevant in this litigation.

Prometheus's Request Nos. 53 and 58-60 seek all documents concerning the REMS for Roxane's ANDA products and LOTRONEX® including all documents considered by Roxane in designing, developing or implementing Roxane's REMS and communications between the FDA and Roxane concerning the design, development or implementation of Roxane's REMS. Roxane has agreed to produce non-privileged documents that concern the REMS that Roxane has proposed to the FDA or the REMS for LOTRONEX® and all communications with the FDA regarding Roxane's proposed REMS. For the reasons discussed above, Roxane maintains its objection to producing *draft* REMS documents that were never filed with the FDA. Similarly, documents regarding REMS systems that Roxane considered, but never pursued, are irrelevant.

The cases cited by Prometheus with respect to these document requests are inapposite. Those cases do not support Prometheus's baseless argument that ***all*** documents regarding an ANDA product are relevant when only specific ***method of use*** claims are at issue or that draft

FDA filings are relevant. For example, in *Astellas,* a ***compound*** patent was at issue, and the motion to compel discovery in that case concerned requests for admissions and inadequately prepared 30(b)(6) witnesses, not document requests. Two other cases cited by Prometheus, *Conopco* and *Kamatani*, were not ANDA litigations and did not involve discovery disputes about a party's API or formulation documents or about the relevance of draft regulatory filings.

For the above reasons, the Court should deny Prometheus's request "that Roxane be ordered to produce all documents and things responsive to the full scope of Prometheus' Requests Nos. 2-4, 53 and 58-60."

B. Documents Concerning Sales/Revenue Projections and Business Plans (Request Nos. 22-24)

Prometheus's Request Nos. 22-24 seek the production of, *inter alia*, Roxane's projections, marketing plans, sales or revenue estimates and promotional materials. Roxane has agreed to produce documents concerning actual LOTRONEX® sales. Roxane has no marketing plans, business plans, strategic plans, planned marketing, sales catalogs or promotional materials for its ANDA products, and has never sold any alosetron products.

Prometheus argues that Roxane's projections and estimates of sales or revenue for Roxane's ANDA products are relevant to infringement and commercial success, but Prometheus is wrong. The basis of this infringement action is Roxane's submission of ANDA No. 200-652 to the FDA. Roxane's subjective forecasts and analyses of market and sales information have no bearing on the issues of infringement and commercial success. Commercial success requires proof of actual sales of LOTRONEX®, not forecasts, and whether a nexus exists between those sales and the claimed subject matter of the '770 patent. For the foregoing reasons, the Court should deny Prometheus's requests for documents regarding projections and estimates of sales or revenue for Roxane's ANDA products.

C. Roxane's "Knowledge" Regarding The '770 Patent Infringement and Validity (Interrogatories Nos. 3 and 10)

Interrogatory No. 3 seeks the identification of all persons employed or associated with Roxane who are knowledgeable about Roxane's beliefs, claims or defenses of non-infringement and invalidity of the '770 patent and the facts relating thereto. Interrogatory No. 10 requests that Roxane describe the circumstances under which Roxane became aware of the reexamination proceedings concerning the patent-in-suit and the individuals employed by Roxane who are most knowledgeable about the same. Prometheus argues that the requested information is relevant to the issue of inducement. Prometheus is wrong. There is no dispute that Roxane knows about the '770 patent. How Roxane learned about the reexamination of the '770 patent is not relevant to any issue in this case. In any event, such information is privileged.

Moreover, Roxane's infringement and invalidity contentions are clear, and Roxane has already provided them to Prometheus. Roxane has also provided Prometheus with the names of

employees knowledgeable about the use of alosetron. Beyond that, any Roxane employee's specific knowledge of Roxane's defenses is based on communications with counsel and is irrelevant to the issue of inducement.

For the foregoing reasons, Prometheus's requests with respect to Interrogatory Nos. 3 and 10 should be denied.

D. Identification of Opinions or Advice Regarding The '770 Patent (Interrogatory No. 5)

Interrogatory No. 5 seeks identification of any legal opinions or advice regarding the '770 patent. Interrogatory No. 5 is premature. The Court's Scheduling Order states "parties shall produce reliance on counsel discovery no later than 30 days after entry of the Markman ruling pursuant to L. Civ. P. 3.8." Local Patent Rule 2.3(d) states:

> A party may object, ... to responding to the following categories of discovery requests ... on the ground that they are premature in light of the timetable provided in the Local Patent Rules:
>
> **(d)** Requests seeking to elicit the identification of any advice of counsel, and related documents.

Moreover, legal opinions regarding the '770 patent are privileged, and will be identified in Roxane's schedule of withheld documents. For the foregoing reasons, the Court should deny Prometheus's request with respect to Interrogatory No. 5.

Respectfully yours,

Charles M. Lizza

Exhibits

cc: All Counsel (via e-mail)

Exhibit A

Exhibit A

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PROMETHEUS LABORATORIES INC., Plaintiff, v. ROXANE LABORATORIES, INC., Defendant.	Civil Action No. 11-230 (FSH)(PS) Civil Action No. 11-1241 (FSH)(PS) **PROMETHEUS' FIRST SET OF REQUESTS FOR THE PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1-87)**

Plaintiff Prometheus Laboratories Inc., by and through its undersigned attorneys, hereby requests that defendant Roxane Laboratories, Inc. produce for inspection and copying, pursuant to Rules 26 and 34 of the Federal Rule of Civil Procedure and the Local Civil Rules of the United States District Court for the District of New Jersey, all documents and tangible things that are set forth in each of the following Requests, within thirty (30) days of these Requests, at the offices of Jones Day, 222 East 41st Street, New York, New York 10017-6702, or as otherwise agreed by counsel.

DEFINITIONS

The following definitions and instructions are to be considered applicable to all specific requests for the production of documents and things:

1. "Prometheus" shall refer to Prometheus Laboratories Inc., and includes any subsidiaries, departments, divisions, present and former officers, directors, trustees, employees, predecessors-in-interest, agents, and/or representatives.

Exhibit A

immunity being claimed, the data and general subject matter of the withheld communication or document, the date of its creation or preparation, and all persons who authored, are shown as copies on the document, or who received the document, or who were present when the communication was made. When any privilege or immunity is claimed, indicate as to the information requested, whether any such documents exist. This shall take the form of a "privilege log."

4. You are instructed to produce documents as they are kept in the usual course of business or to produce documents organized and labeled to correspond with the categories in these requests. In addition, a complete original or copy of each document or thing must be produced, even though only a portion of such document or thing is responsive to one of the numbered requests contained herein.

5. These requests shall be deemed continuing so as to require further and supplemental production by you whenever you acquire or discover additional information or responsive documents between the time of the initial production hereunder and the time of trial in this action. Should you obtain any other documents or information which would supplement or modify the documents or information supplied by you in response to this request, you are directed to give timely notice of such documents and information and to furnish the additional documents or information to Prometheus without delay.

DOCUMENTS AND THINGS REQUESTED

Request for Production No. 1.

A complete copy of ANDA No. 200-652, including any amendments or supplements thereto.

Request for Production No. 2.

All documents and things concerning ANDA No. 200-652.

Exhibit A

Request for Production No. 3.

All communications between Roxane and the FDA concerning ANDA No. 200-652, and all documents and things concerning such communications.

Request for Production No. 4.

All documents and things concerning Roxane's ANDA Products.

Request for Production No. 5.

All documents and things concerning LOTRONEX®.

Request for Production No. 6.

All documents and things concerning alosetron.

Request for Production No. 7.

All communications between Roxane and any party, including the FDA, concerning alosetron or any alosetron-containing product and all documents and things concerning such communications.

Request for Production No. 8.

Documents and things sufficient to identify each person that advised or assisted in the preparation or filing of any submission to the FDA concerning Roxane's ANDA Products or in the decision to prepare and file any such submission.

Request for Production No. 9.

All documents and things concerning Roxane's decision to seek FDA approval to market Roxane's ANDA Products.

Request for Production No. 10.

All documents and things concerning any analysis, study, evaluation, or opinion conducted or rendered by or for Roxane relating to Roxane's ANDA Products, including, but not limited to, all documents concerning certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Exhibit A

Request for Production No. 18.

All documents and things concerning the safety of administering any alosetron product.

Request for Production No. 19.

All documents and things concerning the efficacy of administering any alosetron product.

Request for Production No. 20.

All documents and things, including, but not limited to, publications, research notebooks, research summaries, and reports, concerning the development of Roxane's ANDA Products.

Request for Production No. 21.

All documents and things concerning Roxane's marketing or planned or proposed marketing of any alosetron product, including Roxane's ANDA Products.

Request for Production No. 22.

Projections, predictions, or estimates of sales or revenues that Roxane's ANDA Products may generate if approved by the FDA and all documents and things concerning any projections, predictions or estimates.

Request for Production No. 23.

Projections, predictions, or estimates of the expected sales for Roxane's ANDA Products and all documents and things concerning such projections, predictions, or estimates.

Request for Production No. 24.

Any business plan or strategic plan relating to the marketing and sale of Roxane's ANDA Products and all documents and things concerning such plans.

Request for Production No. 25.

All documents and things concerning any problems, difficulties, or delays that Roxane has experienced in preparing to bring to market Roxane's ANDA Products.

Exhibit A

Request for Production No. 50.

All documents and things concerning the use of Roxane's ANDA Products, including, but not limited to, the use of Roxane's ANDA Products for the treatment of medical conditions, including non-constipated female IBS.

Request for Production No. 51.

Any comparative study, *in vitro* or *in vivo*, that compares any element, aspect, or attribute of Roxane's ANDA Products to any other alosetron product, including Prometheus' LOTRONEX® product and all documents and things concerning such study.

Request for Production No. 52.

All documents and things concerning the manner in which Roxane intends for Roxane's ANDA Products to be administered to patients.

Request for Production No. 53.

All documents and things concerning any Roxane REMS or any REMS for any other alosetron product, including the REMS for Prometheus' LOTRONEX® product.

Request for Production No. 54.

Any requests for proposals, or RFPs, from any person or entity concerning any Roxane REMS and all documents and things concerning such requests and RFPs.

Request for Production No. 55.

Any response to any requests for proposal, or RFPs, from any person or entity concerning any Roxane REMS and all documents and things concerning such requests or RFPs.

Request for Production No. 56.

All documents and things concerning any restrictions or regulations on the distribution of or access to Roxane's ANDA Products, including restrictions or regulations based on patient population or disease states.

Exhibit A

Request for Production No. 57.

All documents and things concerning any call centers, including any call-center scripts, or other planned responses to doctor, patient, or other inquiries regarding Roxane's ANDA Products or alosetron.

Request for Production No. 58.

All documents and things considered or relied on by Roxane in designing, developing, or implementing any Roxane REMS or any other program designed to prevent, restrict, or regulate access to Roxane's ANDA Products.

Request for Production No. 59.

All documents and things concerning the creation, design, development, or implementation of any Roxane REMS or any other program designed to prevent, restrict, or regulate access to Roxane's ANDA Products.

Request for Production No. 60.

Communications between Roxane and the FDA or any other person, concerning the design, development, or implementation of any Roxane REMS or any other program designed to prevent, restrict, or regulate access to Roxane's ANDA Products and all documents concerning such communications.

Request for Production No. 61.

Any labeling, medication guides, product inserts, instructions sheets, brochures, or other materials relating to administration or use of Roxane's ANDA Products and all documents and things concerning such labeling, guides, inserts, sheets, brochures and other materials.

Request for Production No. 62.

Any labeling, medication guides, product inserts, instructions sheets, brochures, or other materials describing any version of any Roxane REMS and all documents and things concerning

Exhibit A

Request for Production No. 84.

All documents and things provided to Roxane from Cipla concerning alosetron.

Request for Production No. 85.

All documents and things provided to Cipla from Roxane concerning alosetron.

Request for Production No. 86.

Any agreements between Roxane and Cipla relating to alosetron and all documents and things concerning such agreements.

Request for Production No. 87.

All documents concerning United States Patent No. 6,175,014.

Dated: June 17, 2011

By: _____

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Exhibit B

Exhibit B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PROMETHEUS LABORATORIES INC., Plaintiff, v. ROXANE LABORATORIES, INC., Defendant.	Civil Action No. 11-230 (FSH)(PS) Civil Action No. 11-1241 (FSH)(PS) **PROMETHEUS' FIRST SET OF INTERROGATORIES (NOS. 1-15)**

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and the Local Civil Rules for the United States District Court for the District of New Jersey, Plaintiff Prometheus Laboratories Inc., by and through its undersigned attorneys, requests that defendant Roxane Laboratories, Inc. answer the following interrogatories within thirty (30) days after service hereof.

DEFINITIONS AND INSTRUCTIONS

1. The following definitions and instructions are to be considered applicable to all interrogatories contained in this request:

2. Prometheus hereby incorporates by reference all Definitions and Instructions set forth in Prometheus' First Set of Requests for the Production of Documents and Things as though fully set forth herein.

3. With regard to each interrogatory, should the answer require the identification of a person or entity, state the full name, business address, occupation, telephone number, and relationship to Roxane of each such person or entity, and describe in detail all the facts

Exhibit B

Interrogatory No. 3.

Identify all persons employed by or otherwise associated with Roxane who are most knowledgeable about Roxane's beliefs, assertions, claims, or defenses of non-infringement, patent invalidity, and unenforceability, or of the facts concerning the assertions, claims or defenses, including any affirmative defenses, made in Roxane's Answers in this litigation; and for each person identify the matters about which the person has knowledge.

Interrogatory No. 4.

Identify any search, study, investigation, experiments, or research that Roxane is aware of concerning the effect of alosetron, including, but not limited to, any such study, investigation, experiments, or research conducted by or on behalf of Roxane concerning the role of alosetron in treating IBS, including non-constipated female IBS, or the blood plasma concentration, safety, or efficacy of any alosetron product.

Interrogatory No. 5.

Identify any written or oral opinion or advice regarding the meaning, interpretation, validity, invalidity, infringement, lack of infringement, enforceability, lack of enforceability, construction, or scope of any of the claims of the patent-in-suit, including the date, the preparer, speaker, author, and all recipients of each opinion or advice.

Interrogatory No. 6.

Describe in detail each requirement of any REMS or any other program designed to prevent, restrict, or regulate access to Roxane's ANDA Products, and identify all persons employed by or otherwise associated with Roxane most knowledgeable concerning such REMS or other program.

Interrogatory No. 7.

Identify all persons employed by or otherwise associated with Roxane who are most knowledgeable about any notification pursuant to 21 USC § 355(j)(2)(B)(ii) to Prometheus and/or Roxane's certification under 21 USC § 355(j)(2)(A)(vii)(IV) with respect to the patent-in-suit, including the underlying facts therein, and the preparation of such a notification and / or certification, and for each person identify the matters about which the person has knowledge.

Interrogatory No. 8.

Identify all persons employed by or otherwise associated with Roxane who are most knowledgeable about the use of Prometheus' LOTRONEX® product and/or Roxane's ANDA Products for the treatment of IBS, and for each person identify the matters about which the person has knowledge.

Interrogatory No. 9.

Identify all persons employed by or otherwise associated with Roxane who are most knowledgeable about Roxane's noninfringement and/or invalidity contentions, including any assertions therein and any facts concerning the assertions made therein, and for each person identify the matters about which the person has knowledge.

Interrogatory No. 10.

Describe in detail the circumstances under which Roxane became aware of the reexamination proceedings concerning the patent-in-suit, including the issuance of a reexamination certificate, and identify all persons employed by or otherwise associated with Roxane most knowledgeable concerning such circumstances.

Exhibit B

Interrogatory No. 15.

Identify all persons involved in, and the persons who are most knowledgeable of, Roxane's collection and production of documents and things in response to Prometheus' discovery requests in this action, including the persons most knowledgeable concerning Roxane's corporate structure and any organizational charts produced by Roxane.

Dated: June 17, 2011

By: _____

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Prometheus Laboratories Inc.

Exhibit C

Exhibit C

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PROMETHEUS LABORATORIES INC., Plaintiff, v. ROXANE LABORATORIES, INC., Defendant.	Civil Action No. 2:11-CV-00230-CCC-JAD Civil Action No. 2:11-CV-01241-CCC-JAD

ROXANE'S RESPONSES TO PROMETHEUS'S FIRST SET OF REQUESTS FOR THE PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1-87)

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Defendant Roxane Laboratories, Inc. ("Roxane") hereby responds to Plaintiff Prometheus Laboratories Inc.'s ("Prometheus" or "Plaintiff") First Set Of Requests For The Production Of Documents And Things (Nos. 1-87) (the "Requests") served on June 17, 2011. With respect to all Requests, Roxane reserves the right to produce documents and things by making them available for inspection and copying by Plaintiff at the offices of GOODWIN PROCTER LLP, the New York Times Building, 620 Eighth Avenue, New York, New York 10018. Otherwise, Roxane will send to the offices of Plaintiff's counsel, JONES DAY, a copy of those relevant, responsive documents and things in Roxane's possession, custody, or control that have been located after reasonable search and inquiry, except to the extent such documents are protected by the attorney-client privilege or work-product immunity or otherwise are subject to objections set forth in this response.

Exhibit C

REQUEST FOR PRODUCTION NO. 2:

All documents and things concerning ANDA No. 200-652.

RESPONSE TO REQUEST FOR PRODUCTION NO. 2:

Roxane objects to this Request on the ground that it is duplicative of Request No. 1, and on the ground that it seeks documents that are duplicative of Roxane's ANDA, amendments and supplements thereto, and correspondence between Roxane and the FDA regarding its ANDA, which were produced pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling Order. Roxane also objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Roxane further objects to this Request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not relevant to the infringement, invalidity, or unenforceability of the '770 patent, to the extent it seeks the production of draft FDA filings and draft correspondence between Roxane and the FDA, and to the extent it seeks documents not related to the uses for which Roxane seeks FDA approval for its ANDA products. Roxane further objects to this Request to the extent it seeks the production of documents and things that are not within Roxane's possession, custody or control.

Subject to and without waiving the above Specific and General Objections, Roxane responds that pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling Order, Roxane has produced its ANDA No. 200-652, amendments and supplements thereto, and correspondence between Roxane and the FDA regarding Roxane's ANDA. Roxane will continue to produce amendments and supplements to ANDA No. 200-652 and communications between FDA and Roxane regarding ANDA No. 200-652 pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling Order. Roxane further responds that it will make

reasonable efforts to locate and produce, if found, relevant, non-privileged, responsive documents and things that are within Roxane's possession, custody or control, dated before January 14, 2011, and that concern ANDA No. 200-652, to the extent they are relevant to the infringement, invalidity, or unenforceability of the '770 patent or related to the uses for which Roxane seeks approval for its ANDA products.

REQUEST FOR PRODUCTION NO. 3:

All communications between Roxane and the FDA concerning ANDA No. 200-652, and all documents and things concerning such communications.

RESPONSE TO REQUEST FOR PRODUCTION NO. 3:

Roxane objects to this Request to the extent it is duplicative of at least Request No. 2, and to the extent that it seeks documents and things that are duplicative of the correspondence between Roxane and the FDA that were produced pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling Order. Roxane also objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Roxane further objects to this Request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because it seeks documents not relevant to the infringement, invalidity, or unenforceability of the '770 patent, because it seeks the production of draft correspondence between Roxane and the FDA, and because it seeks documents not related to the uses for which Roxane seeks FDA approval for its ANDA products. Roxane further objects to this Request on the ground that it seeks the production of documents and things that are not within Roxane's possession, custody or control.

Subject to and without waiving the above Specific and General Objections, Roxane responds that pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling

Order, Roxane has produced communications between Roxane and the FDA regarding Roxane's ANDA. Roxane will continue to produce communications between FDA and Roxane regarding ANDA No. 200-652 pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling Order. Roxane further responds that it will make reasonable efforts to locate and produce, if found, relevant, non-privileged, responsive documents and things that are within Roxane's possession, custody or control, dated before January 14, 2011, and that concern communications between Roxane and the FDA concerning ANDA No. 200-652, to the extent they are relevant to the infringement, invalidity, or unenforceability of the '770 patent or related to the uses for which Roxane seeks approval for its ANDA products.

REQUEST FOR PRODUCTION NO. 4:

All documents and things concerning Roxane's ANDA Products.

RESPONSE TO REQUEST FOR PRODUCTION NO. 4:

Roxane objects to this Request on the ground that it is duplicative of at least Request Nos. 1-3, and on the ground that it seeks documents that are duplicative of Roxane's ANDA, amendments and supplements thereto, and correspondence between Roxane and the FDA regarding its ANDA, which were produced pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling Order. Roxane also objects to this Request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because it seeks documents not relevant to the infringement, invalidity, or unenforceability of the '770 patent, because it seeks the production of draft FDA filings and draft correspondence between Roxane and the FDA, and because it seeks documents not related to the uses for which Roxane seeks FDA approval for its ANDA products. Roxane further objects to this Request on the ground that it seeks the production of documents and things that are not

within Roxane's possession, custody or control. Roxane further objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity.

Subject to and without waiving the above Specific and General Objections, Roxane responds that pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling Order, Roxane has produced its ANDA No. 200-652, amendments and supplements thereto, and correspondence between Roxane and the FDA regarding Roxane's ANDA. Roxane will continue to produce amendments and supplements to ANDA No. 200-652 and communications between FDA and Roxane regarding ANDA No. 200-652 pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling Order. Roxane further responds that it will make reasonable efforts to locate and produce, if found, relevant, non-privileged, responsive documents and things that are within Roxane's possession, custody or control, dated before January 14, 2011, and that concern Roxane's ANDA products, to the extent they are relevant to the infringement, invalidity, or unenforceability of the '770 patent or related to the uses for which Roxane seeks approval for its ANDA products.

REQUEST FOR PRODUCTION NO. 5:

All documents and things concerning LOTRONEX®.

RESPONSE TO REQUEST FOR PRODUCTION NO. 5:

Roxane objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Roxane also objects to this Request on the ground that it seeks the production of documents and things that are not within Roxane's possession, custody or control. Roxane further objects to this Request on the ground that it calls for production of

reasonable efforts to locate and produce, if found, non-privileged, relevant, responsive documents that are within Roxane's possession, custody or control, dated before January 14, 2011, and that concern the development of Roxane's ANDA Products, to the extent they are relevant to the infringement, invalidity, or unenforceability of the '770 patent, or related to the uses for which Roxane seeks FDA approval for its ANDA products.

REQUEST FOR PRODUCTION NO. 21:

All documents and things concerning Roxane's marketing or planned or proposed marketing of any alosetron product, including Roxane's ANDA Products.

RESPONSE TO REQUEST FOR PRODUCTION NO. 21:

Roxane objects to this Request on the ground that it is duplicative of at least Request No. 2. Roxane also objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Roxane further objects to this Request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because it seeks documents not relevant to the infringement, invalidity, or unenforceability of the '770 patent, and because it seeks documents not related to the uses for which Roxane seeks FDA approval for its ANDA products.

Subject to and without waiving the above Specific and General Objections, Roxane responds that it will not produce documents responsive to this Request beyond what it may produce in response to other Requests.

REQUEST FOR PRODUCTION NO. 22:

Projections, predictions, or estimates of sales or revenues that Roxane's ANDA Products may generate if approved by the FDA and all documents and things concerning any projections, predictions or estimates.

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RESPONSE TO REQUEST FOR PRODUCTION NO. 22:

Roxane objects to this Request on the ground that it is duplicative of at least Request No. 2. Roxane also objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Roxane further objects to this Request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because it seeks documents not relevant to the infringement, invalidity, or unenforceability of the '770 patent, and because it seeks documents not related to the uses for which Roxane seeks FDA approval for its ANDA products.

Subject to and without waiving the above Specific and General Objections, Roxane responds that it will not produce documents responsive to this Request beyond what it may produce in response to other Requests.

REQUEST FOR PRODUCTION NO. 23:

Projections, predictions, or estimates of the expected sales for Roxane's ANDA Products and all documents and things concerning such projections, predictions, or estimates.

RESPONSE TO REQUEST FOR PRODUCTION NO. 23:

Roxane objects to this Request on the ground that it is duplicative of at least Request Nos. 2 and 22. Roxane also objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Roxane further objects to this Request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because it seeks documents not relevant to the infringement, invalidity, or unenforceability of the '770 patent, and because it seeks documents not related to the uses for which Roxane seeks FDA approval for its ANDA products.

Subject to and without waiving the above Specific and General Objections, Roxane responds that it will not produce documents responsive to this Request beyond what it may produce in response to other Requests.

REQUEST FOR PRODUCTION NO. 24:

Any business plan or strategic plan relating to the marketing and sale of Roxane's ANDA Products and all documents and things concerning such plans.

RESPONSE TO REQUEST FOR PRODUCTION NO. 24:

Roxane objects to this Request on the ground that it is duplicative of at least Request Nos. 2 and 21. Roxane also objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Roxane further objects to this Request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because it seeks documents not relevant to the infringement, invalidity, or unenforceability of the '770 patent, and because it seeks documents not related to the uses for which Roxane seeks FDA approval for its ANDA products.

Subject to and without waiving the above Specific and General Objections, Roxane responds that it will not produce documents responsive to this Request beyond what it may produce in response to other Requests.

REQUEST FOR PRODUCTION NO. 25:

All documents and things concerning any problems, difficulties, or delays that Roxane has experienced in preparing to bring to market Roxane's ANDA Products.

RESPONSE TO REQUEST FOR PRODUCTION NO. 25:

Roxane objects to this Request on the ground that it is duplicative of at least Request No. 2. Roxane also objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other

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RESPONSE TO REQUEST FOR PRODUCTION NO. 52:

Roxane objects to this Request on the ground that it is duplicative of at least Request Nos. 46, 49 and 50. As such, Roxane hereby incorporates its objections and responses to Request Nos. 46, 49 and 50.

REQUEST FOR PRODUCTION NO. 53:

All documents and things concerning any Roxane REMS or any REMS for any other alosetron product, including the REMS for Prometheus' LOTRONEX® product.

RESPONSE TO REQUEST FOR PRODUCTION NO. 53:

Roxane objects to this Request on the ground that it is duplicative of at least Request Nos. 5, 6, 46 and 49-52, and on the ground that it seeks documents that are duplicative of Roxane's ANDA, amendments and supplements thereto, and correspondence between the FDA and Roxane regarding Roxane's ANDA, which were produced pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling Order. Roxane also objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Roxane further objects to this Request because it calls for production of documents concerning "any alosetron product" on the grounds that it is overbroad, unduly burdensome, oppressive and not reasonably calculated to lead to the discovery of admissible evidence. Roxane further objects to this Request because it calls for production of documents concerning "any Roxane REMS" on the grounds that it is overbroad, unduly burdensome, oppressive and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the above Specific and General Objections, Roxane responds that pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling Order, Roxane has produced its ANDA No. 200-652, amendments and supplements thereto, and

correspondence between Roxane and the FDA regarding Roxane's ANDA. Roxane will continue to produce amendments and supplements to ANDA No. 200-652 and communications between FDA and Roxane regarding ANDA No. 200-652 pursuant to the Local Rules of this Court and the Court's June 3, 2011 Scheduling Order. Roxane further responds that it will make reasonable efforts to locate and produce, if found, non-privileged, relevant, responsive documents that are within Roxane's possession, custody or control, dated before January 14, 2011, and that concern the REMS that Roxane has proposed to the FDA with respect to ANDA No. 200-652 or the REMS for LOTRONEX®.

REQUEST FOR PRODUCTION NO. 54:

Any requests for proposals, or RFPs, from any person or entity concerning any Roxane REMS and all documents and things concerning such requests and RFPs.

RESPONSE TO REQUEST FOR PRODUCTION NO. 54:

Roxane objects to this Request on the ground that it is duplicative of Request Nos. 6 and 53. Roxane also objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Roxane further objects to this Request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because it seeks documents not relevant to the infringement, invalidity, or unenforceability of the '770 patent, and because it seeks documents not related to the uses for which Roxane seeks FDA approval for its ANDA products or the REMS that Roxane has proposed to the FDA. Roxane further objects to this Request because it calls for production of documents concerning "any Roxane REMS" on the grounds that it is overbroad, unduly burdensome, oppressive and not reasonably calculated to lead to the discovery of admissible

produce, if found, non-privileged, relevant, responsive documents that are within Roxane's possession, custody or control, dated before January 14, 2011, and that relate to call centers that will be responsible for Roxane's ANDA products.

REQUEST FOR PRODUCTION NO. 58:

All documents and things considered or relied on by Roxane in designing, developing, or implementing any Roxane REMS or any other program designed to prevent, restrict, or regulate access to Roxane's ANDA Products.

RESPONSE TO REQUEST FOR PRODUCTION NO. 58:

Roxane objects to the terms "designing," "developing," and "implementing" and the phrase "prevent, restrict, or regulate access" as overly broad, vague and ambiguous. Roxane also objects to this Request on the ground that it is duplicative of at least Request Nos. 49, 52, 53 and 56. As such, Roxane hereby incorporates its objections and responses to Request Nos. 49, 52, 53 and 56.

REQUEST FOR PRODUCTION NO. 59:

All documents and things concerning the creation, design, development, or implementation of any Roxane REMS or any other program designed to prevent, restrict, or regulate access to Roxane's ANDA Products.

RESPONSE TO REQUEST FOR PRODUCTION NO. 59:

Roxane objects to the terms "creation," "design," "development," and" implementation" and the phrase "prevent, restrict, or regulate access" as overly broad, vague and ambiguous. Roxane also objects to this Request on the ground that it is duplicative of at least Request Nos. 49, 52, 53, 56 and 58. As such, Roxane hereby incorporates its objections and responses to Request Nos. 49, 52, 53, 56 and 58.

REQUEST FOR PRODUCTION NO. 60:

Communications between Roxane and the FDA or any other person, concerning the design, development, or implementation of any Roxane REMS or any other program designed to

prevent, restrict, or regulate access to Roxane's ANDA Products and all documents concerning such communications.

RESPONSE TO REQUEST FOR PRODUCTION NO. 60:

Roxane objects to this Request on the ground that it is duplicative of at least Request Nos. 2-6, 49, 52, 53, 56, 58 and 59. As such, Roxane hereby incorporates its objections and responses to Request Nos. 2-6, 49, 52, 53, 56, 58 and 59.

REQUEST FOR PRODUCTION NO. 61:

Any labeling, medication guides, product inserts, instructions sheets, brochures, or other materials relating to administration or use of Roxane's ANDA Products and all documents and things concerning such labeling, guides, inserts, sheets, brochures and other materials.

RESPONSE TO REQUEST FOR PRODUCTION NO. 61:

Roxane objects to this Request on the ground that it is duplicative of at least Request Nos. 2, 6, 16, 46, 49 and 50. As such, Roxane hereby incorporates its objections and responses to Request Nos. 2, 6, 16, 46, 49 and 50.

REQUEST FOR PRODUCTION NO. 62:

Any labeling, medication guides, product inserts, instructions sheets, brochures, or other materials describing any version of any Roxane REMS and all documents and things concerning such labeling, guides, inserts, instructions, sheets, brochures, and other materials.

RESPONSE TO REQUEST FOR PRODUCTION NO. 62:

Roxane objects to this Request because it calls for production of documents concerning "any Roxane REMS" on the grounds that it is overbroad, unduly burdensome, oppressive and not reasonably calculated to lead to the discovery of admissible evidence. Roxane also objects to the phrase "any version" as overly broad, vague and ambiguous. Roxane further objects to this Request on the ground that it is duplicative of at least Request Nos. 2-6, 49, 52, 53, 56 and 58-60. As such, Roxane hereby incorporates its objections and responses to Request Nos. 2-6, 49, 52, 53, 56 and 58-60.

RESPONSE TO REQUEST FOR PRODUCTION NO. 86:

Roxane objects to this Request on the ground that it is duplicative of at least Request Nos. 78 and 82. As such, Roxane hereby incorporates its objections and responses to Request Nos. 78 and 82.

REQUEST FOR PRODUCTION NO. 87:

All documents concerning United States Patent No. 6,175,014.

RESPONSE TO REQUEST FOR PRODUCTION NO. 87:

Roxane objects to this Request on the ground that it seeks documents that are immune from discovery under the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Roxane also objects to this Request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because it seeks documents concerning U.S. Patent No. 6,175,014, which are not relevant to the infringement, invalidity, or unenforceability of the '770 patent, and are not related to the uses for which Roxane seeks FDA approval for its ANDA products.

Subject to and without waiving the above Specific and General Objections, Roxane responds that it will not produce documents responsive to this Request beyond what it may produce in response to other Requests.

Dated: July 20, 2011

By: Michael B. Cottler

Attorneys for Defendant Roxane Laboratories, Inc.

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Scott A. Warren
Michael B. Cottler
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Exhibit C

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Exhibit C

CERTIFICATE OF SERVICE

The undersigned, counsel for Roxane, hereby certifies that copies of **Roxane's Responses To Prometheus's First Set Of Interrogatories (Nos. 1-15)** and **Roxane's Responses to Prometheus's First Set Of Requests For The Production Of Documents And Things (Nos. 1-87)** were caused to be served, via electronic mail, on July 20, 2011 upon the following attorneys of record:

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_____

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Exhibit D

Exhibit D

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PROMETHEUS LABORATORIES INC., Plaintiff, v. ROXANE LABORATORIES, INC., Defendant.	Civil Action No. 11-0230 (CCC)(JAD) Civil Action No. 11-1241 (CCC)(JAD) **HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY**

ROXANE'S RESPONSES TO PROMETHEUS'S FIRST SET OF INTERROGATORIES (NOS. 1-15)

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and the Local Civil Rules for the United States District Court for the District of New Jersey, Defendant Roxane Laboratories Inc. ("Roxane"), by and through its undersigned attorneys, hereby responds to the First Set of Interrogatories (Nos. 1-15) ("First Set of Interrogatories") served by Plaintiff Prometheus Laboratories Inc. ("Prometheus" or "Plaintiff").

Roxane's responses to these Interrogatories are based upon reasonable and diligent inquiry and the best knowledge or information known or readily available to Roxane as of the date of this response. Further investigation may reveal additional responsive information and documents. Roxane reserves the right to continue discovery and investigation into this matter and to present at trial or otherwise, in accordance with the Federal Rules of Civil Procedure, additional information discovered after the date of this response. Roxane therefore reserves the right to supplement, modify, change, amend, or alter these responses.

vague and ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roxane, for purposes of this Response, construes this term as "the persons who are most knowledgeable of." Roxane also objects to this Interrogatory on the grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because the Interrogatory seeks information not relevant to the infringement, validity, or enforceability of the '770 patent.

Subject to and without waiving the above Specific and General Objections and to the extent Roxane understands this Interrogatory, Roxane responds that:

Elizabeth Ernst is the person employed by Roxane who is most knowledgeable regarding communications between Roxane and the FDA regarding ANDA No. 200-652 and Roxane's ANDA products.

Roxane reserves the right to supplement this Response based on further investigation.

Interrogatory No. 3.

Identify all persons employed by or otherwise associated with Roxane who are most knowledgeable about Roxane's beliefs, assertions, claims, or defenses of non-infringement, patent invalidity, and unenforceability, or of the facts concerning the assertions, claims or defenses, including any affirmative defenses, made in Roxane's Answers in this litigation; and for each person identify the matters about which the person has knowledge.

Response to Interrogatory No. 3.

Roxane objects to this Interrogatory on the ground that it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privilege or immunity. In particular, this Interrogatory seeks Roxane's legal analyses, thoughts, notes, memorandums, etc. regarding Roxane's noninfringement and invalidity positions in this matter. Roxane also objects to this Interrogatory as overly broad, vague and ambiguous as to the meaning of the term "otherwise associated with." Roxane, for purposes of this Response, construes this to mean the same as "employed by." Roxane further objects to this

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Interrogatory on the grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because the Interrogatory seeks information not properly the subject of an interrogatory.

Subject to and without waiving the above Specific and General Objections and to the extent Roxane understands this Interrogatory, Roxane refers Plaintiff to Roxane's Invalidity and Non-Infringement Contentions dated July 8, 2011. Roxane will not otherwise provide information responsive to this Interrogatory beyond what it may provide in response to other Interrogatories.

Interrogatory No. 4.

Identify any search, study, investigation, experiments, or research that Roxane is aware of concerning the effect of alosetron, including, but not limited to, any such study, investigation, experiments, or research conducted by or on behalf of Roxane concerning the role of alosetron in treating IBS, including non-constipated female IBS, or the blood plasma concentration, safety, or efficacy of any alosetron product.

Response to Interrogatory No. 4

Roxane objects to this Interrogatory on the ground that it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privilege or immunity. Roxane also objects to this Interrogatory because it seeks the identity of "any search, sturdy, investigation, experiments or research Roxane is aware of concerning the effect of alosetron" on the ground that it is overbroad, unduly burdensome, oppressive and not reasonably calculated to lead to the discovery of admissible evidence. Roxane, for purposes of this Response, will provide information regarding human alosetron studies that Roxane has conducted or directed a third party to conduct. Roxane further objects to this Interrogatory as overly broad, vague and ambiguous as to the meaning of the term "the effect of alosetron." Roxane, for purposes of this Response, construes this to mean the same as "efficacy or safety of alosetron." Roxane further objects to this Interrogatory as overly broad,

Roxane's ANDA, which contains information relating to human alosetron studies. *See, e.g.*, ROX_ALOS000164-201, ROX_ALOS000216-2223 and ROX_ALOS002625-5575.

Roxane reserves the right to supplement this Response based on further investigation.

Interrogatory No. 5.

Identify any written or oral opinion or advice regarding the meaning, interpretation, validity, invalidity, infringement, lack of infringement, enforceability, lack of enforceability, construction, or scope of any of the claims of the patent-in-suit, including the date, the preparer, speaker, author, and all recipients of each opinion or advice.

Response to Interrogatory No. 5.

Roxane objects to this Interrogatory on the ground that it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privilege or immunity. In particular, this Interrogatory seeks both Roxane's and Roxane's outside counsels' legal analyses, thoughts, notes, memoranda, etc. regarding Roxane's noninfringement and invalidity positions in this matter. Roxane also objects to this Interrogatory to the extent it asks Roxane to decide whether to rely on opinion of counsel before it is required to do so under the Court's June 3, 2011 Scheduling Order. Roxane further objects to this Interrogatory on the grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because the Interrogatory only seeks information not relevant to the infringement, validity, or enforceability of the '770 patent. Roxane further objects to this Interrogatory as overly broad, vague and ambiguous as to the meaning of the phrase "any written or oral opinion or advice." Roxane, for purposes of this Response, construes this to mean "any written or oral legal opinion or advice requested by or provided to Roxane." Roxane further objects to this Interrogatory because it seeks information that Roxane will produce in the form of its privilege log pursuant to the Court's June 3, 2011 Scheduling Order.

Exhibit D

Subject to and without waiving the above Specific and General Objections and to the extent Roxane understands this Interrogatory, Roxane responds that it will not provide information responsive to this Interrogatory beyond what it may provide in response to other Interrogatories.

Interrogatory No. 6.

Describe in detail each requirement of any REMS or any other program designed to prevent, restrict, or regulate access to Roxane's ANDA Products, and identify all persons employed by or otherwise associated with Roxane most knowledgeable concerning such REMS or other program.

Response to Interrogatory No. 6.

Roxane objects to this Interrogatory on the ground that it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privilege or immunity. Roxane also objects to this Interrogatory as overly broad, vague and ambiguous as to the meaning of the term "otherwise associated with." Roxane, for purposes of this Response, construes this to mean the same as "employed by." Roxane further objects to this Interrogatory on the grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because the Interrogatory seeks information not relevant to the infringement, validity, or enforceability of the '770 patent, and because it seeks information not related to the REMS that Roxane has proposed to the FDA regarding its ANDA products. Pursuant to Federal Rule of Civil Procedure 33(d), Roxane further objects to this Interrogatory because it seeks information that can be derived or ascertained by Prometheus from documents produced in this action by Roxane as readily as it could be derived by Roxane.

Subject to and without waiving the above Specific and General Objections and to the extent Roxane understands this Interrogatory, Roxane responds that:

Exhibit D

Subject to and without waiving the above Specific and General Objections and to the extent Roxane understands this Interrogatory, Roxane refers Plaintiff to Roxane's Invalidity and Non-Infringement Contentions dated July 8, 2011. Roxane will not otherwise provide information responsive to this Interrogatory beyond what it may provide in response to other Interrogatories.

Interrogatory No. 10.

Describe in detail the circumstances under which Roxane became aware of the reexamination proceedings concerning the patent-in-suit, including the issuance of a reexamination certificate, and identify all persons employed by or otherwise associated with Roxane most knowledgeable concerning such circumstances.

Response to Interrogatory No. 10.

Roxane objects to this Interrogatory on the ground that it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other applicable privilege or immunity. Roxane further objects to this Interrogatory as overly broad, vague and ambiguous as to the meaning of the term "otherwise associated with." Roxane, for purposes of this Response, construes this to mean the same as "employed by." Roxane further objects to this Interrogatory on the grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence because the Interrogatory seeks information that is not relevant to the infringement, validity, or enforceability of the '770 patent.

Subject to and without waiving the above Specific and General Objections and to the extent Roxane understands this Interrogatory, Roxane responds that it will not provide information responsive to this Interrogatory beyond what it may provide in response to other Interrogatories.

Exhibit D

Dated: July 20, 2011

By: Michael B. Cottler

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